

PATENT

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Applicant: GENE P. DIPOTO Confirmation No.: 7977
Serial No.: 10/686,063 Examiner: VY Q. BUI
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Title: CANNULA FOR RECEIVING SURGICAL INSTRUMENTS

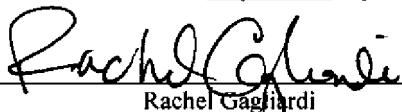
PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By _____



Rachel Gagliardi

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

The rejection of claims 56-74 and 76-110 as being anticipated by Kogasaka et al. is in error because Kogasaka et al. does not teach the identical method steps recited in the claims, as is required for anticipation. In the Response to Arguments section on page 4 of the final Office Action, the Examiner asserts that when elastic members 444 are expanded to strip tissue, members 444 and mesh 443 must apply a pressure on the tissue and therefore retract/move tissue away from the original position of the tissue, thus inherently there must be a step of retracting/moving the tissue away from the original position of the tissue. Applicants respectfully disagree.

The Examiner is considering the specific method steps recited in the claims to be inherent in Kogasaka et al. Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or

characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

(Emphasis added). Applicants submit that the claimed method steps, in particular the step of "moving a plurality of discrete segments of the retractor away from each other to retract tissue adjacent the spinal location", is not necessarily present in Kogasaka et al. It appears the Examiner is asserting that the claimed method steps could be performed by the system of Kogasaka et al., which is not a proper basis for rejection. The Examiner's assertion that "there must be a step of retracting/moving the tissue" has no basis in the disclosure of Kogasaka et al. Further, the Examiner has not provided any reasoning to support this assertion. Kogasaka et al. teach:

When the surgery stripper with the above-described constitution is pressed lightly against a site of a body cavity from which it is desired to remove tissues, it is possible to strip the site of tissues.

See column 65, lines 53-56. Kogasaka et al. thus does not appear to teach expanding a retractor to retract tissues, but rather appears to teach a stripper insert that provides fluid feed and suction for stripping or removing tissues. Kogasaka et al. also teach:

Although in this embodiment the elastic member 444 in the form of a cylinder has slits on its perimeter, the elastic member 444 may be composed of a plurality of strips which are then arranged into a cylinder.

See column 70, lines 39-43. The device of Kogasaka et al. does not appear to have a plurality of discrete segments that necessarily retract tissue when moved away from each other, as asserted by the Examiner. The elastic member 444 with slits 448 of Kogasaka et al. appears to provide a means of delivering and removing fluid from an operation site. Further, because Kogasaka et al. do not appear to teach a structure that inherently and necessarily retracts tissue, the reference cannot be deemed to teach the specific method steps recited in the claims.

In particular, Applicants submit that the claimed method step of "moving a plurality of discrete segments of the retractor away from each other to retract tissue" is not inherent in Kogasaka et al.

Independent claim 65 recites the separate steps of, "pivoting the distal portion relative to the proximal portion" and "expanding at least a portion of the distal portion". Kogasaka et al. do not appear to teach or suggest these separate method steps. The Examiner asserts that Fig. 111B shows distal portion spring members 444 pivoting about proximal portion located at ring 445. Fig. 111B shows the expansion of elastic member 444, but does not appear to show a separate pivoting step. Kogasaka et al. thus do not appear to teach each of the specific steps recited in claim 65.

Regarding independent claim 87, the Examiner asserts that a notch, by definition, can be broadly understood as a step or degree of expanding of discrete segments 444. The Examiner also asserts that spring member 444 and mesh 443 expand step by step when handling rod 447 is pulled proximally, and each "pulling step" defines a notch as recited in the claims. Applicants respectfully disagree. MPEP 2111 states:

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." >The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

415 F.3d at 1316, 75 USPQ2d at 1329. See also< *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000).

Emphasis added. The Examiner's interpretation of "notches" as merely step of expansion is inconsistent with the specification and inconsistent with the interpretation of one of ordinary

skill in the art. The specification teaches at, for example, paragraphs 0031 and 0036 (as published):

[0031] The arcuate slot 100 (FIGS. 3 and 4) has three notches or stops 106 between the ends 102 and 104. The notches 106 define three expanded conditions of the second tubular portion 40. The notches 106 extend in directions transverse to the arcuate direction in which the slot 100 extends. Although the present invention shows three stops 106, it is contemplated that the slot could have any number of stops.

[0036] In the expanded conditions (FIG. 1), the guide member 114 engages one of the stops 106 and is located in one of the notches 106 in the arcuate slot 100 in the second tubular portion 40. It is also contemplated that the guide member 114 could engage one of the stops 106 and be located between adjacent notches 106. The stops 106 retain the guide member 114 in one of a plurality of positions relative to the slot 100 and resist movement of the guide member from one of the plurality of positions relative to the slot. Accordingly, the stops 106 resist contraction of the second tubular portion 40.

See also FIGS. 3 and 4. Applicants submit that in view of the teachings of the specification, one of ordinary skill in the art would not interpret the claimed “notches” as merely degrees of expansion, as asserted by the Examiner. The Examiner’s interpretation of the claim terms is in error.

Independent claims 74 and 107 and the claims dependent thereon were restricted in the Office Action mailed 12/12/07 and were not elected. The Examiner appears to have withdrawn the restriction because all claims 56-110 are included in the final rejections. Further, the Examiner specifically addressed the Applicants’ previous arguments regarding independent claim 107. The Examiner asserts that Fig. 111A of Kogasaka et al. shows a clearance between mesh/1st connector/2nd connector 443 and spring member 444, and Fig. 111B shows a reduced clearance between 443 and 444, thus inherently there must be a relative moving between 443 and 444 during expanding motion of spring member 444. Applicants respectfully disagree. The Examiner appears to be interpreting mesh 443 as somehow being both first and second connectors. Kogasaka et al. teach:

As shown in Fig. 111A, the external surface of the treatment segment 442 is covered with a mesh 443, and in its interior is placed an elastic member 444... The mesh 443 is knitted by a thread made of a resin such as nylon and has a contractility.

See column 69, lines 47-52. Applicants submit that Kogasaka et al. teach a knitted mesh 443, and do not appear to teach first and second connectors as recited in claim 107. The disclosure of Kogasaka et al. does not support the Examiner's interpretation. Kogasaka et al. do not appear to teach or suggest moving any of the segments 444 along a connector, as is recited in the claim. The rejection is thus in error.

For at least the reasons set forth above, Kogasaka et al. do not appear to teach the identical method steps in the same detail as is recited in claims 56-74 and 76-110. Kogasaka et al. thus cannot be seen to anticipate the claims. Further, there is no motivation for one of ordinary skill in the art to modify the method of Kogasaka et al. to achieve the claimed method steps. Reconsideration and withdrawal of the rejection are respectfully requested.

The Examiner has not addressed Applicants' previous arguments regarding the rejection dependent claim 75. The Examiner appears to be taking Official Notice with respect to claim 75, asserting that the concept of using a plurality of dilators is well known and expected in the art. Applicants submit that the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known, especially in the context of the present invention. Per MPEP 2144.03(C), Applicants respectfully traverse the taking of Official Notice and requested the Examiner provide documentary evidence supporting the rejection, however no evidence has yet been provided. This rejection is thus in error.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance.

Respectfully submitted,

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By his attorney,

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